

APR - 7 2010

Ethicon Endo-Surgery, LLC
Traditional 510(k) Premarket Notification Harmonic FOCUS shears

K 100597

510(k) Summary

Company: Ethicon Endo-Surgery, LLC
475 Calle C
Guaynabo, PR 00969

Contact: Marcia Arentz, RAC
Regulatory Affairs Portfolio Leader
Ethicon Endo-Surgery
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Date Prepared: March 1, 2010

Device Name: Trade Name: Harmonic FOCUS™ shears
Common or Usual Name: Ultrasonic Surgical Instrument
Classification Name: Electrosurgical Cutting and Coagulation
Device [21 CFR 878.4400 (GEI/LFL)]
Device Class: Class II

Predicate Devices: Harmonic FOCUS™ shears (K063192)
Harmonic Blades (K060245, K012176, K990362)
Olympus Ultrasonic Surgical System (K031305)
Conmed Electrosurgical Pencils (K041868)
ArthroCare ENT Coblator/Plasma Wands (K070374, K030108)

Purpose of Submission: To modify the Indications for Use Statement to include the specific indication to use the device in otorhinolaryngology procedures. The device design is essentially unchanged from the previously cleared FOCUS device.

Device Description: The Harmonic FOCUS™ Curved Shears is a sterile, single patient use instrument consisting of a soft grip scissor handle housing assembly with two hand controls (MIN for minimum power level and MAX for maximum power level). The instrument has a curved blade and clamp arm with Teflon pad. The instruments working length is 9cm with a 16mm active blade length. The FOCUS instrument allows for the cutting and coagulation of vessels up to and including 5mm in diameter. The Harmonic FOCUS Shears are designed for use with a generator capable of providing electrical energy to the FOCUS device and with a handpiece that converts the electrical energy to mechanical energy.

Indications for Use: The Harmonic FOCUS™ Curved Shears are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, *otorhinolaryngologic (ENT)*, plastic, pediatric, gynecologic, urologic, exposure to orthopedic structures (such as spine and joint space), and other open procedures.

Technological Characteristics: The Harmonic FOCUS™ Curved Shears is the same device as the predicate Harmonic FOCUS™ Curved Shears with minor changes to the design and assembly drawings. The function and intended use of the device have not been changed. The FOCUS shears are designed for use with the Harmonic® Scalpel Generator and the Harmonic Handpiece. The generator provides electrical energy to the Handpiece which creates ultrasonic vibration (55,500 Hz) in the blade. The mechanical energy of the moving blade is converted into thermal energy which is used to cut and coagulate soft tissues.

The Harmonic FOCUS™ device is similar in design and utilizes the same ultrasonic technology as the predicate Harmonic FOCUS device, the predicate Harmonic Scalpel Blades and the predicate Olympus Ultrasonic Surgical System shears. The Harmonic FOCUS device is also similar to electrosurgical devices such as the Conmed electrosurgical Pencils and the Arthrocare ENT Coblator/Plasma wands because they all use electrical energy to cut and coagulate tissues.

Performance Data: The design of the Harmonic FOCUS Shears is essentially unchanged and the performance data provided in K063192 is still applicable to the device. The Harmonic FOCUS shears device will seal vessels up to and including 5mm in diameter.

Clinical Literature: An assessment of published clinical literature demonstrates that there is a considerable body of knowledge and experience that show the use of ultrasonic Harmonic technology in otorhinolaryngological (ENT) procedures is as safe and effective as predicate technology for use.

Substantial Equivalence

In establishing substantial equivalence of the Harmonic FOCUS shears to the predicate devices, Ethicon Endo-Surgery evaluated the intended use, the indications for use, the technological characteristics and the energy requirements of the systems. The Harmonic FOCUS is substantially equivalent to the predicates because they share the same intended use and technological characteristics. The use of Harmonic FOCUS shears in otorhinolaryngologic (ENT) procedures does not raise any new types of questions of safety and effectiveness compared with predicate devices currently used for these procedures.



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Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

Ethicon Endo-Surgery, LLC
% Ms. Marcia Arentz, RAC
Regulatory Affairs Portfolio Leader
4545 Creek Road
Cincinnati, Ohio 45242

Re: K100597

Trade/Device Name: Harmonic FOCUS™ Shears
Regulatory Class: Unclassified
Product Code: LFL, GEI
Dated: March 01, 2010
Received: March 02, 2010

Dear Ms. Arentz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

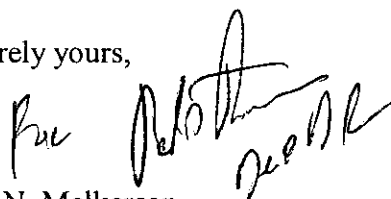
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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', is written over the typed name and title.

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100597

Device Name: Harmonic FOCUS™ Shears

Indications for Use:

The HARMONIC FOCUS™ Shears are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, otorhinolaryngologic (ENT), plastic, pediatric, gynecologic, urologic, exposure to orthopedic structures (such as spine and joint space), and other open procedures.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for mkm
(Division Sign-Off)

Division of Surgical, Orthopedic,
and Restorative Devices

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(Posted November 13, 2003)

510(k) Number K100597